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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,382	04/12/2004	Christian Georg	P04,0140	2858

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SCHIFF HARDIN LLP
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, IL 60606

EXAMINER

LAMPRECHT, JOEL

ART UNIT	PAPER NUMBER
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3737

MAIL DATE	DELIVERY MODE
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04/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/822,382	Applicant(s) GEORG ET AL.	
	Examiner JOEL M. LAMPRECHT	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 7, the position of the markers are defined with respect to a non-claimed element (the implant). Regarding claim 12, the claim is directed to defining an unclaimed element such as the implant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (US 2001/0016203 A1) in view of Krause (US 6,701,174 B1). Lee et al discloses the use of x-ray detectable metallic markers *both* on an implant and on or in the bone itself for the purpose of allowing for assessment of the impact of the implant on the health of the bone structure. Lee uses implanted hydroxyapatite-coated implants and other so-disposed structures for the purpose of providing an x-ray detectable assessment tool for bone health over the course of a treatment (0059). Focus should be directed to the measure of the "degree of radiolucency" and later evaluation methods which are directed at assessment of bone health and implant impact on the bone. Lee et al does not disclose the method itself for assessing position change of the implant, though they do mention all of the surgically implanted tools for which to do so, and so attention is directed to the secondary reference by Krause et al, which does disclose the use of post-surgical x-rays from two-directions to calibrate positional relationships of surgically implanted fixation devices for a patient. Coordinate data are used to verify positional relationships (Col 20 Line 1-65) and assess whether or not the implant has shifted. Iterative implementations of the assessment methods of Krause et al determine *if* a positional change as occurred (which would entail motion of the marker). The generation of a bone model which forms a 3d model from multiple projection images initially, is updated post-surgery by using a two-dimensional view of the bone and implant to assess deviation (Col 20 Line 1-38). The methods used allow for either AP or

lateral views to be used to detect the markers and assess deviation (Col 20 Line 38-55). It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the teachings of Krause et al, with the motivations and system of Lee for the purpose of providing effective post-operative assessment of bone health.

Response to Arguments

Applicant's arguments filed 8/27/07 have been fully considered and are responded to below. The Scarborough reference has been replaced by the Lee et al reference due to the motivations provided by the Lee reference for assessment and the inclusion of metallic spheres and markers in the environment and region of the bone itself. The arguments levied against the Krause et al reference, namely that Krause et al requires a 3d reconstruction in order to make an assessment post-surgically, the Examiner respectfully disagrees. Taking into account the disclosure of column 20 of the Krause et al reference, it is clear that with only a post-surgical lateral view, an assessment of the deviation of lack-there-of of the implant can be made. The fixation device of Krause has the x-ray markers disposed thereupon which allows for assessment of the fixation of the implant or fixator as compared to the stored image data to assess relative position of the x-ray implantable markers (see distribution) and make a determination of the position of the detectable markers (and thereby a degree of probability of motion of the marker). The disclosure of Krause is not directed to intermediate levels of probability, such as the output of a 10%, 0.6 or 2/3rds chance of motion, but provides a decision as to whether a positional change has occurred, which entails a probability estimation on the order of "true or false" (1 or 0 respectively).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

JML